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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS 3444-FN]

Medicare Program; Application by The Joint Commission (TJC) for Continued CMS Approval of its Home Infusion Therapy (HIT) Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This final notice announces our decision to approve The Joint Commission (TJC) for continued recognition as a national accrediting organization that accredits suppliers of home infusion therapy (HIT) services that wish to participate in the Medicare or Medicaid programs.

DATES: The approval announced in this final notice is effective December 15, 2023 through December 15, 2029.

FOR FURTHER INFORMATION CONTACT:

Shannon Freeland, (410) 786-4348.

SUPPLEMENTARY INFORMATION:

I. Background

Home infusion therapy (HIT) is a treatment option for Medicare beneficiaries with a wide range of acute and chronic conditions. Section 5012 of the 21st Century Cures Act (Pub. L. 114-255, enacted December 13, 2016) added section 1861(iii) to the Social Security Act (the Act), establishing a new Medicare benefit for HIT services. Section 1861(iii)(1) of the Act defines "home infusion therapy" as professional services, including nursing services; training and education not otherwise covered under the Durable Medical Equipment (DME) benefit; remote monitoring; and other monitoring services. Home infusion therapy must be furnished by a

qualified HIT supplier and furnished in the individual's home. Sections 1861(iii)(A) and (B) require that the individual (patient) must:

- Be under the care of an applicable provider (that is, physician, nurse practitioner, or physician assistant); and
- Have a plan of care established and periodically reviewed by a physician in coordination with the furnishing of home infusion drugs under Part B, which prescribes the type, amount, and duration of infusion therapy services that are to be furnished.

Section 1861(iii)(3)(D)(i)(III) of the Act requires that a qualified HIT supplier be accredited by an accrediting organization (AO) designated by the Secretary in accordance with section 1834(u)(5) of the Act.

Section 1834(u)(5)(A) of the Act identifies factors for designating HIT AOs and in reviewing and modifying the list of designated HIT AOs. These statutory factors are as follows:

- The ability of the accrediting organization to conduct timely reviews of HIT accreditation applications.
- The ability of the accrediting organization to take into account the capacities of HIT suppliers located in a rural area (as defined in section 1886(d)(2)(D) of the Act).
- Whether the accrediting organization has established reasonable fees to be charged to HIT suppliers applying for accreditation.
- Such other factors as the Secretary determines appropriate.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit HIT suppliers furnishing HIT not later than January 1, 2021. Section 1861(iii)(3)(D)(i)(III) of the Act requires a “qualified home infusion therapy supplier” to be accredited by a CMS-approved AO, pursuant to section 1834(u)(5) of the Act.

The Joint Commission's (TJC's) current term of approval for their Home Infusion Therapy accreditation program expires December 15, 2023.

II. Approval of Deeming Organization

Section 1834(u)(5) of the Act and § 488.1010 require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide CMS with the necessary data.

Our rules at 42 CFR 488.1020(a) require that we publish, after receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. Pursuant to our rules at 42 CFR 488.1010(d), we have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

III. Provisions of the Proposed Notice

In the July 18, 2023 **Federal Register** (88 FR 45907), we published a proposed notice announcing The Joint Commission's (TJC's) request for continued recognition as a national accrediting organization providing home infusion therapy (HIT) services that wish to participate in the Medicare or Medicaid programs. In that proposed notice, we detailed our evaluation criteria. Under section 1834(u)(5) the Act and in our regulations at § 488.1010, we conducted a review of TJC's Medicare HIT accreditation application in accordance with the criteria specified by our regulations, which included, but are not limited to the following:

- An administrative review of TJC's:

++ Corporate policies;

++ Financial and human resources available to accomplish the proposed surveys;

++ Procedures for training, monitoring, and evaluation of its HIT surveyors;

++ Ability to investigate and respond appropriately to complaints against accredited HITs; and

++ Survey review and decision-making process for accreditation.

- The equivalency of TJC's standards for HIT as compared with CMS' HIT conditions for certification.

- TJC's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of TJC's to CMS standards and processes, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ TJC's processes and procedures for monitoring a HIT supplier found out of compliance with TJC's program requirements.

++ TJC's capacity to report deficiencies to the surveyed HIT facilities and respond to the facility's evidence of standards compliance in a timely manner.

++ TJC's capacity to provide CMS with electronic data and reports necessary for effective assessment and interpretation of the organization's survey process.

++ TJC's capacity to adequately fund required surveys.

++ TJC's policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced, and

++ TJC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require (including corrective action plans or TJC's evidence of standards compliance).

- The adequacy of TJC's staff and other resources, and its financial viability.

- TJC's agreement or policies for voluntary and involuntary termination of suppliers.

- TJC's agreement or policies for voluntary and involuntary termination of the HIT AO program.

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1834(u)(5) of the Act, the July 18, 2023, proposed notice also

solicited public comments regarding whether TJC's requirements met or exceeded the Medicare conditions for participation for HIT. We received one comment in response to our proposed notice. The comment and our response follows:

Comment: The commenter believes that continued approval of home infusion therapy is one that greatly benefits those on Medicare and Medicaid. The commenter stated that it also provides many benefits to all including less travel, less staff needed, comfort of your home, and less exposure to others for the immune compromised.

Response: We thank this commenter for their comment in support of the HIT program.

V. Provisions of the Final Notice

A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TJC's HIT accreditation requirements and survey process with the Medicare CfCs of 42 CFR part 486, and the survey and certification process requirements of part 488. Our review and evaluation of TJC's HIT application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, TJC has completed revising its standards and certification processes to meet the conditions at:

- Section 486.520 (b), to address the requirement that the plan of care must be established by a physician prescribing the type, amount, and duration for HIT.
- Section 486.520 (c), to address the requirement that the plan of care must be periodically reviewed by the physician.
- Section 486.525 (a), to address the requirement that the HIT suppliers to be available 7 days a week, 24 hours a day.
- Section 486.525 (a)(1), to address the requirement of all professional services, including nursing services, to be available to the home infusion patient.

- Section 486.525 (a)(2), to address the requirement for patient education and training to be available for patients on a 7 day a week, 24 hour a day basis in accordance with the plan of care.

- Section 486.525 (a)(3), to address the requirement of remote monitoring for the provision of HIT and home infusion drugs.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that TJC's requirements for HITs meet or exceed our requirements. Therefore, we approve TJC as a national accreditation organization for HITs that request participation in the Medicare program, effective December 15, 2023 through December 15, 2029.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison,

Centers for Medicare & Medicaid Services.

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